91–180. The lower compliance in the testosterone patch group was mostly due to skin reactions from the subjects' records.

TABLE 31

Incidence of Skin-Associated Adverse Events: Day 1 to Day 180 in Patients Who Remained on Initial Treatment

	5.0 g/day T-gel N = 53	10.0 g/day T-gel N = 57	T-Patch N = 73
Total	16 (30.2%)	18 (31.6%)	50 (68.5%)
Application Site Reaction	3 (5.7%	3 (5.3%)	48 (65.8%)
Acne	1 (1.9%)	7 (12.3%)	3 (4.1%)
Rash	4 (7.5%)	4 (7.0%)	2 (2.7%)
Skin Disorder	2 (3.8%)	1 (1.8%)	1 (1.4%)
Skin Dry	2 (3.8)	0 (0.0%)	1 (1.4%)
Sweat	0 (0.0%)	2 (3.5%)	0 (0.0%)
Reaction Unevaluable	2 (3.6%)	1 (1.7%)	0 (0.0%)
Cyst	0 (0.0%)	0 (0.0%)	2 (2.7%)

Example 2

Gel Delivery Dosage Forms and Devices

The present invention is also directed to a method for dispensing and packaging the gel. In one embodiment, the invention comprises a hand-held pump capable of delivering about 2.5 g of testosterone gel with each actuation. In another embodiment, the gel is packaged in foil packets comprising a polyethylene liner. Each packet holds about 2.5 g of testosterone gel. The patient simply tears the packet along a perforated edge to remove the gel. However, because isopropyl myristate. binds to the polyethylene liner, additional isopropyl myristate is added to the gel in order to obtain a pharmaceutically effective gel when using this delivery embodiment. Specifically, when dispensing the gel via the foil packet, about 41% more isopropyl myristate is used in the gel composition (i.e., about 0.705 g instead of about 0.5 g in Table 5), to compensate for this phenomenon.

The composition can also be dispensed from a rigid multi-dose container (e.g., with a hand pump) having a larger foil packet of the composition inside the container. Such larger packets also comprise a polyethylene liner as above.

Both embodiments permit a patient to deliver accurate but incremental amounts of gel (e.g., either 2.5 g, 5.0 g, 7.5 g, etc.) to the body. These delivery mechanisms thus permit the gel to be administered in unit dose form depending on the particular needs and characteristics of the patient.

Although the invention has been described with respect to specific embodiments and examples, it should be appreciated that other embodiments utilizing the concept of the present invention are possible without departing from the scope of the invention. Th present invention is defined by the claimed elements, and any and all modifications, variations, or equivalents that fall within the true spirit and scope of the underlying principles.

We claim:

1. A pharmaceutical composition, consisting essentially of:

a. about 0.5% to about 10% testosterone;

b. about 30% to about 98% alcohol selected from the group consisting of ethanol and isopropanol;

c. about 0.1% to about 5% isopropyl myristate;

d. about 1% to about 5% sodium hydroxide; and

e. about 0.1% to about 5% of a gelling agent,

wherein the percentages of components are weight to weight of the composition.

2. The composition as recited in claim **1**, wherein the testosterone is present in a concentration selected from the group consisting of about 0.5%, 1%, 2%, 3%, 4%, 5%, 6%, 7%, 8%, 9%, and 10% weight of the composition.

3. The composition as recited in claim **1**, wherein the composition is contained in a packet selected from the group consisting of a unit dose packet or multiple dose packet.

4. The composition as recited in claim **1**, therein the isopropyl myristate is present in a concentration selected from the group consisting of about 0.5%, 1%, 2%, 3%, 4%, and 5% weight to weight of the composition.

5. The composition as recited in claim **1**, wherein the isopropyl myristate is present in a concentration of about 0.5% weight to weight of the composition.

6. The composition as recited in claim **1**, wherein the gelling agent is selected from the group consisting of polyacrylic acid and carboxymethylcellulose present in a concentration of about 0.1% to about 5% weight to weight of the composition.

7. The composition as recited in claim **1**, wherein the composition is the form of a gel.

8. The composition as recited in claim **1**, wherein the gelling agent is polyacrylic acid present in a concentration of about 1% weight to weight of the composition.

9. A hydroalcoholic gel formulation, consisting essentially of:

a. about 1% to about 2% testosterone;

b. about 50% to about 75% ethanol;

c. about 0.5% to about 2% isopropyl myristate;

d. about 1% to about 3% sodium hydroxide;

e. about 0.5% to about 2% polyacrylic acid; and

f. water in an amount sufficient to make the formulation 100%;

wherein the percentages of components are weight to weight of the formulation.

10. A unit dose packet comprising inner and outer surfaces, and a pharmaceutical composition inside the packet, the composition consisting essentially of:

a. about 0.5% to about 5% testosterone;

b. about 30% to about 98% ethanol;

c. about 0.1% to about 5% isopropyl myristate;

d. about 1% to about 5% sodium hydroxide; and

e. about 0.1% to about 5% of a gelling agent;

wherein the percentages of components are weight to weight of the composition.

11. The packet as recited in claim **10**, wherein the composition weighs about 1.0 gram to about 10.0 grams.

12. The packet as recited in claim **10**, wherein the composition weighs about 2.5 grams to about 5.0 grams.

13. The packet as recited in claim **10**, wherein the composition is in a form of a gel.

14. The packet as recited in claim **10**, wherein the testosterone is present in a concentration selected from the group consisting of about 0.5%, 1%, 2%, 3%, 4%, and 5% weight to weight of the composition.

15. The packet recited claim **10**, wherein the isopropyl myristate is present in a concentration of about 0.5% weight to weight of the composition.

16. The packet as recited in claim **10**, wherein the gelling agent is selected from the group consisting of polyacrylic acid and carboxymetliylcellulose.

17. The packet as recited in claim **10**, wherein the gelling agent is about 1% polyacrylic acid weight to weight of the composition.